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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/480,472	06/06/1995	SHERROL H. MCDONOUGH	213/066	9286

21365 7590 06/16/2004  
GEN PROBE INCORPORATED  
10210 GENETIC CENTER DRIVE  
SAN DIEGO, CA 92121

EXAMINER

MARSCHER, ARDIN H

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

**Application No.**

08/480,472

**Applicant(s)**

MCDONOUGH ET AL.

**Examiner**

Ardin Marschel

**Art Unit**

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See attached listing is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) See attached listing is/are allowed.
- 6) ☒ Claim(s) See attached listing is/are rejected.
- 7) ☒ Claim(s) See attached listing is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                         |                                                                             |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)          |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. <u>2/24/04</u> .                                     |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____.                                                            | 6) <input type="checkbox"/> Other: _____.                                   |

Art Unit: 1631

### **DETAILED ACTION**

Due to the newly applied rejections set forth below, the finality of the Office action, mailed 12/29/03, is hereby withdrawn.

Applicants' arguments, filed 2/24/04, have been fully considered and they are deemed to be persuasive to overcome previous rejections of record. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

### **SUMMARY OF CLAIMS STATUS**

Pending claims: 39-42, 48-51, 54-56, 67-73, 75, 78-80, 82-84, 86, 88-90, 92, 93, 95, 96, 98-162, 164-174, 176-213, and 216-231

Allowed claims: 42, 55, 56, 75, 78-80, 82, 83, 95, 96, 100-149, 151-157, 164-167, 169-172, 174, 177-179, 185, 187-191, 195, 196, 199-203, 216-221, and 227-231

Rejected claims: 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213, and 222-226

Objected to claims: 48-51, 54, 93, and 99

Canceled claims: 1-38, 43-47, 52, 53, 57-66, 74, 76, 77, 81, 85, 87, 91, 94, 97, 163, 175, 214, and 215

### **PRIOR ART**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 1631

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 39-41, 67-73, 84, 86, 88-90, 92, 98, 150, 158-162, 168, 173, 176, 180-184, 186, 192-194, 197, 198, 204-213, and 222-226 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boddinghaus et al. [J. Clin. Microbiol. 28:1751 (1990)]; taken in view of Suzuki et al. [J. Bact 170(6):2886 (1988)]; taken further in view of Shah et al. (P/N 5,521,300).

The combination of references of Boddinghaus et al. with Suzuki et al. is reiterated from the previous office action, mailed 12/19/03. Applicants have argued that there is therein no motivation to detect *M. bovis* BCG from other organisms. Shah et al. describes a variety of microorganisms including various *Mycobacteria* species such as tuberculosis, *bovis* BCG, etc. in column 1, line 1, through column 3, line 7, including the motivation and suggestion to distinguish such species including via amplification.

Thus, it would have been obvious at the time of the instant invention to amplify *M. bovis* BCG via its rRNA sequences as set forth in the combination of Boddinghaus et

Art Unit: 1631

al. and Suzuki et al. motivated for such amplification for distinguishing microorganisms as set forth in Shah et al. to result in the practice of the instant invention.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

June 11, 2004

*Ardin H. Marschel* 6/11/04  
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